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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Andrew A. Kumamoto
Cooley Godward LLP
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94360-2155

EXAMINER	
EPPERSON, JON D	
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1627	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)	
09/764,163	BALINT ET AL.	
Examiner	**Art Unit**	
Jon D Epperson	1627	

Office Action Summary

File Copy

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-79* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The fax number is (703) 308-4315. A fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, Supervisory Patent Examiner, at (703) 308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14 are drawn to a first method for identifying a second oligopeptide to which a first oligopeptide binds, classified variously, for example, in class 424, subclass 192.1 or class 435, subclass 69.7 or class 435, subclass 192.1.

II. Claims 15-20 are drawn to a second method for identifying a second oligopeptide to which a first oligopeptide binds, classified variously, for example, in class 435, DIG 46 and 47.

III. Claims 21-23 are drawn to a method of identifying a third oligopeptide to which a first oligopeptide and a second oligopeptide simultaneously bind, for example, in class 424, subclass 192.1 or class 435, subclass 69.7 or class 435, subclass 192.1.

IV. Claims 24-49 (in part) and 54-56 (in part) are drawn to a product described as an enzyme activation system or an intracellular signal transduction biosensor, wherein said circularly permutated maker protein reassembles to form a functionally reconstituted marker protein that produces a detectable signal upon

the association of said first oligopeptide with said second oligopeptide, classified variously, for example, in class 424, subclass 192.1 or class 435, subclass 69.7 or class 435, subclass 192.1.

V. Claims 24-49 (in part) and 54-56 (in part) are drawn to a product described as an enzyme activation system or an intracellular signal transduction biosensor, wherein said circularly permutated maker protein reassembles to form a functionally reconstituted marker protein that produces a detectable signal upon simultaneous association of said first oligopeptide and said second oligopeptide with a third oligopeptide, classified variously, for example, in class 424, subclass 192.1 or class 435, subclass 69.7.

VI. Claims 50-53 (in part) are drawn to a product described as an enzyme activation system wherein at least one of said first oligopeptide or said second oligopeptide is a member of a library, wherein said circularly permutated maker protein reassembles to form a functionally reconstituted marker protein that produces a detectable signal upon the association of said first oligopeptide with said second oligopeptide, classified variously, for example, in class 424, subclass 192.1 or class 435, subclass 69.7 or class 435, DIG 46 and 47.

VII. Claims 50-53 (in part) are drawn to a product described as an enzyme activation system wherein at least one of said first oligopeptide or said second oligopeptide is a member of a library, wherein said circularly permutated maker protein reassembles to form a functionally reconstituted marker protein that produces a detectable signal upon simultaneous association of said first oligopeptide and said

second oligopeptide with a third oligopeptide, classified variously, for example, in class 424, subclass 192.1 or class 435, subclass 69.7 or class 435, subclass 192.1.

VIII. Claims 57, 59-65, 72-75 are drawn to a product described as an expression cassette or nucleic acid sequence encoding the fusion protein, classified in class 536, subclass 23.4.

IX. Claim 58 is drawn to a product described as an expression cassette for a third polypeptide that simultaneously binds said first polypeptide and said second polypeptide (nucleotide sequence for protein), classified in class 536, subclass 23.4.

X. Claim 66 is drawn to a product described as a plasmid for the fusion protein, classified variously, for example, class 435, subclass 476, 481, and 488..

XI. Claim 67 is drawn to a product described as a plasmid for the "third protein", classified variously, for example, class 435, subclass 476, 481, and 488.

XII. Claims 68 and 70 are drawn to a product described as a host cell comprising a plasmid for the fusion protein, classified variously, for example, class 435, subclass 71.1, 328, and 488.

XIII. Claims 69 and 71 are drawn to a product described as a host cell comprising a plasmid for the "third protein", classified variously, for example, class 435, subclass 71.1, 328, and 488.

XIV. Claims 76-79 are drawn to a method for high-throughput identification of compounds that inhibit phosphorylation-regulated cell signal transducers, classified variously, for example, class 435, subclass 134.1, 479, and 488.

2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I and II are different methods. The methods are different because they use different steps, require different reagents and/or will produce different results. In this case, the method of Group II employs an extra step, uses members of a "proteome library", which is not required by the method of Group I. As a result, Group II requires different reagents (reagents for making and monitoring proteome libraries) that are not required by Group I. Furthermore, Groups II will produce different results than Group I in situations where members of the proteome library are required. Therefore, Groups I and II have different issues regarding patentability and enablement and represent patentably distinct subject matter.

4. Groups I and III are different methods. The methods are different because they use different steps, require different reagents and/or will produce different results. In this case, the method of Group III employs an extra step, requires a third oligopeptide to bind to first and second oligopeptides, which is not required by the method of Group I. As a result, Group III requires a different reagent (a third oligopeptide) that is not required by Group I. Furthermore, Group III will produce different results than Group I in situations where this third oligopeptide is required. Therefore, Groups I and III have different issues regarding patentability and enablement and represent patentably distinct subject matter.

5. Groups II and III are different methods. The methods are different because they use different steps, require different reagents and/or will produce different results. In this case, the method of Group III employs one step that is not utilized by Group II, requires a third oligopeptide to bind to first and second oligopeptides. Likewise, the method of Group II employs one step that is not utilized by Group IV, requires using members of a proteome library. As a result, Group III requires a different reagent (a third oligopeptide) that is not required by Group II. Furthermore, Group II requires a different reagent (a proteome library) that is not required by Group III. In addition, Group III will produce different results than Group II in situations where a third oligopeptide is required. Likewise, Group II will produce different results than Group I in situations where a proteome library is required. Therefore, Groups II and IV have different issues regarding patentability and enablement and represent patentably distinct subject matter.

6. Groups I-III and IV-VII represent separate and distinct inventions because Groups I-III claim a method, whereas Groups IV-V claim products. However, if applicant argues that Groups I-III and IV-VII are related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using the product, for example, the applicant has shown that the products i.e., Groups IV-VII can be used for many purposes that involve protein-protein interactions i.e., to study ligand-mediated

assembly of multi-protein complexes, to activate enzymes, to screen libraries, to study signal transduction pathways, etc..

7. Groups IV and V represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. In the instant case, Group V requires a "third oligopeptide" that is not required by Group IV. As a result, the properties of Groups IV and V differ because Group V requires a quasi-ternary complex to form from the first, second, and third oligopeptides, whereas Group IV does not. Furthermore, the synthetic methodology for making Group V requires an extra step i.e., the synthesis of a third peptide. Finally, the use of Group V will differ from Group IV in situations where a third oligopeptide is required. Therefore, Groups IV-V have different issues regarding patentability and enablement and represent patentably distinct subject matter.

8. Groups VI and VII represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. In the instant case, Group VII requires a "third oligopeptide" that is not required by Group VI. As a result, the properties of Groups VI and VII differ because Group VII requires a quasi-ternary complex to form from the first, second, and third oligopeptides, whereas Group VI does not. Furthermore, the synthetic methodology for making Group VII requires an extra step i.e., the synthesis of a third peptide. Finally, the use of Group VII will differ from Group VI in situations where a third oligopeptide is required. Therefore, Groups VI-VII have different issues regarding patentability and enablement and represent patentably distinct subject matter.

9. Groups IV-V and VI-VII represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. In the instant case, Groups VI-VII require a library, whereas Groups IV-V do not. A library of compounds is completely different in form and effect than a single compound and has completely different uses. Therefore, Groups IV-V and VI-VII have different issues regarding patentability and enablement and represent patentably distinct subject matter.

10. Groups I-VII and Groups VIII-IX represent separate and distinct inventions because Groups I-III claim a method and Groups IV-VII claim products involving proteins, whereas Groups VIII-IX claim products involving nucleic acid sequences. However, if applicant argues that Groups IV-VII and VIII-IX are related products, the products can be shown to be patentably distinct if they differ in respect to their properties, their use and the synthetic methodology for making them. In the instant case, Groups VIII-IX possess a different core structure (nucleic acid) than Groups IV-VI (protein) and thus have different physical and chemical properties. In addition, Groups VIII-IX can be made by solid-phase nucleotide synthesis, whereas Groups IV-VI can be made using solid-phase peptide synthesis, which requires a different synthetic methodology including different reagents. Therefore, Groups I-VII and VIII-IX have different issues regarding patentability and enablement and represent patentably distinct subject matter.

11. Groups VIII and IX represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. In

the instant case, Groups IX represents a nucleic acid sequence that encodes for a protein, but Group VIII represents a nucleic acid sequence that encodes for a fusion protein. A sequence for a fusion protein is completely different in form and effect than a sequence for a protein (involves encoding regions of more than one protein) and has completely different uses (can combine the characteristics of more than one protein). Therefore, Groups VIII and IX have different issues regarding patentability and enablement and represent patentably distinct subject matter.

12. Groups I-IX and Groups X-XI represent separate and distinct inventions because Groups I-III claim a method and Groups IV-VII claim products involving proteins and Groups VIII-IX claim products involving nucleic acid sequences, whereas Groups X-XI claim products involving plasmids. However, if applicant argues that Groups IV-IX and X-XI are related products, the products can be shown to be patentably distinct if they differ in respect to their properties, their use and the synthetic methodology for making them. In the instant case, Groups X-XI represent plasmids, which can self-replicate in an appropriate host. None of the other products (Groups IV-IX) possess this property. Also, plasmids are not made using solid-phase synthesis, whereas proteins (Groups IV-VI) and short nucleic acid sequences (Groups VIII-IX) can be. Therefore, Groups I-IX and Groups X-XI have different issues regarding patentability and enablement and represent patentably distinct subject matter.

13. Groups X and XI represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. In the instant case, Groups XI represents a plasmid that contains a protein, but Group X represents a

plasmid that contains a fusion protein. A plasmid containing a fusion protein is completely different in form and effect than a plasmid containing a protein (involves encoding regions of more than one protein spliced together) and has completely different uses (can combine the characteristics of more than one protein). Therefore, Groups X and XI have different issues regarding patentability and enablement and represent patentably distinct subject matter.

14. Groups I- XI and Groups XII-XIII represent separate and distinct inventions because Groups I-III claim a method, Groups IV-VII claim products involving proteins, Groups VIII-IX claim products involving nucleic acid sequences, Groups X-XI claim products involving plasmids, whereas Groups XII-XIII claim products involving host cells. However, if applicant argues that Groups IV-XI and XII-XIII are related products, the products can be shown to be patentably distinct if they differ in respect to their properties, their use and the synthetic methodology for making them. In the instant case, Groups XII-XIII represent host cells, which possess a nucleus, cell wall, etc.. None of the other products (Groups IV-XI) possess these properties. Also, host cells are not made in a similar fashion to Groups IV-XI (require different reagents like growth media, etc.). Therefore, Groups I-XI and Groups XII-XIII have different issues regarding patentability and enablement and represent patentably distinct subject matter.

15. Groups XII and XIII represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. In the instant case, Groups XIII represents a cell that contains a protein, but Group XII represents a cell that contains a fusion protein. A cell containing a fusion protein is completely different in

form and effect than a cell containing a protein (involves encoding regions of more than one protein spliced together) and has completely different uses (can combine the characteristics of more than one protein into a single protein unit). Therefore, Groups XII and XIII have different issues regarding patentability and enablement and represent patentably distinct subject matter.

16. Groups I- XIII and Group XIV represent separate and distinct inventions because Groups I-III claim different methods than Group XIV and Groups IV-XIII claim products rather than a method. However, if applicant argues that Groups I-III and XIV are related methods, the methods can be shown to be patentably distinct if each method uses different steps, requires different reagents and/or will produce different results. In the instant case, Group XIV requires method steps that are not required by Groups I-III e.g., monitoring the color of host cells to determine whether a compound inhibits phosphorylation-regulated cell signal transduction. As a result, Group XIV produces different results than Groups I-III. Therefore, Group XIV has different issues regarding patentability and enablement than Groups I-XIII and represents patentably distinct subject matter.

17. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

18. This application contains claims directed to patentably distinct species of the claimed invention for Groups I and II. Election is required as follows.

19. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of fusion protein (claim 1)
Applicant is required to elect, for the purposes of a search, a ***single*** fusion protein species. Applicant must specify ***all*** the regions of the ***single*** fusion protein including the first oligopeptide, second oligopeptide, marker, linker, and break-point regions. Applicant must also specify the N-terminal signal peptide region (if any). Furthermore, applicant ***must*** disclose which claims read on the elected fusion protein. For example, if applicant elects a fusion protein with a tyrosine kinase in the first oligopeptide region, applicant ***must*** indicate that claims 10 and 11 would read on this election.

Subgroup 2: Species of detectable signal (claim 1)
Applicant is required to elect, for the purposes of a search, a ***single*** detectable signal species e.g., phenotypic change, antibiotic resistance, etc.

Subgroup 3: Species of contact location between first and second oligopeptide (claim 2)
A. *In vitro*
B. *In vivo*

Subgroup 4: Species of host cell (see claims 2-3, 5-7 and 9)
Applicant is required to elect, for the purposes of a search, a ***single*** host cell species e.g., *E. coli*. Applicant should ***not*** use broad terms like "bacterial cell" or "eukaryotic cell" when electing the host cell species because these terms represent groups that contain more than one patentably distinct species. Finally, applicant is also required to disclose which claims read on the elected species.

20. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 15 is generic.

Subgroup 5: Species of fusion protein (claim 15)
Applicant is required to elect, for the purposes of a search, a ***single*** fusion protein species. Applicant must specify ***all*** the regions of the ***single*** fusion protein including the first oligopeptide, second oligopeptide, marker, linker, and break-point regions. Applicant

must also specify the N-terminal signal peptide region (if any). Furthermore, applicant ***must*** disclose which claims read on the elected fusion protein.

Subgroup 6: Species of detectable signal (claim 15)
Applicant is required to elect, for the purposes of a search, a ***single*** detectable signal species e.g., phenotypic change, antibiotic resistance, etc.

Subgroup 7: Species of host cell (claims 17-18)
Applicant is required to elect, for the purposes of a search, a ***single*** host cell species e.g., *E. coli*. Applicant should ***not*** use broad terms like "bacterial cell" or "eukaryotic cell" when electing the host cell species because these terms represent groups that contain more than one patentably distinct species. Finally, applicant is also required to disclose which claims read on the elected species.

Subgroup 8: Species of subcellular compartment (claim 18)

A. Cytoplasm
B. Nucleus
C. Endoplasmic reticulum
D. In association with the extracellular membrane

Subgroup 9: Species of proteome library (claim 19)

A. Single chain antibody Fv fragment library
B. Antibody light chain variable region library
C. Peptide library displayed within thioredoxin

21. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 21 is generic.

Subgroup 10: Species of fusion protein (claim 21)
Applicant is required to elect, for the purposes of a search, a ***single*** fusion protein species. Applicant must specify ***all*** the regions of the ***single*** fusion protein including the first oligopeptide, second oligopeptide, marker, linker, and break-point regions. Applicant must also specify the N-terminal signal peptide region (if any). Furthermore, applicant ***must*** disclose which claims read on the elected fusion protein.

Subgroup 11: Species of detectable signal (claim 21)
Applicant is required to elect, for the purposes of a search, a ***single*** detectable signal species e.g., phenotypic change (specify phenotype), antibiotic resistance (specify antibiotic), etc..

Subgroup 12: Species of third oligopeptide (claim 21)

Applicant is required to elect, for the purposes of a search, a ***single*** third oligopeptide species.

Subgroup 13: Species of host cell (claim 23)
Applicant is required to elect, for the purposes of a search, a ***single*** host cell species e.g., *E. coli*. Applicant should ***not*** use broad terms like "bacterial cell" or "eukaryotic cell" when electing the host cell species because these terms represent groups that contain more than one patentably distinct species. Finally, applicant is also required to disclose which claims read on the elected species.

22. If applicant elects the invention of Groups IV or V, applicant is required to elect from the following patentably distinct species. Claim 24 is generic.

Subgroup 14: Species of fusion protein (claims 24, 36 and 54)
Applicant is required to elect, for the purposes of a search, a ***single*** fusion protein species. Applicant must specify ***all*** the regions of the ***single*** fusion protein including the first oligopeptide, second oligopeptide, marker, linker, break-point, and any randomly-encoded regions. Applicant must also specify the N-terminal signal peptide region (if any). Furthermore, applicant ***must*** disclose which claims read on the elected fusion protein. For example, if applicant elects a fusion protein with a tyrosine kinase as the first intracellular polypeptide region, applicant must indicate that claims 55 and 56 read on the election.

Subgroup 15: Species of detectable signal (claim 24)
Applicant is required to elect, for the purposes of a search, a ***single*** detectable signal species e.g., phenotypic change (specify phenotype), antibiotic resistance (specify antibiotics), etc..

Subgroup 16: Species of third oligopeptide (claim 24)
Applicant is required to elect, for the purposes of a search, a ***single*** third oligopeptide species (if any).

Subgroup 17: Species of tripeptide (claim 30)

A. HSE
B. NGR
C. GRE
D. EKR
E. REQ
F. QGN
G. DGR
H. GRR

I. GNS

Note: If Applicant elects a fusion protein (see subgroup 14) wherein said fusion protein possesses a randomly-encoded tripeptide region, applicant must also elect for the purposes of a search, a ***single*** tripeptide species from those listed in subgroup 17 above.

Subgroup 18: Species of β-lactamase (claims 37-38)
If applicant elects a fusion protein (see subgroup 14) wherein said fusion protein possesses a β-lactamase as the marker protein, applicant must also elect for the purposes of a search, a ***single*** β-lactamase species e.g., Type A, TEM-1, etc..

Subgroup 19: Species of β-lactamase mutant (claim 39)

A. K55E
B. P62S
C. M182T

Note: If applicant elects a fusion protein (see subgroup 14) wherein said fusion protein possesses a β-lactamase mutant as the marker protein, applicant must also elect for the purposes of a search, a ***single*** β-lactamase mutant species from those listed in subgroup 19 above.

Subgroup 20: Species of junction (claims 40 and 41)

A. N52/S53
B. Q99/N100
C. P174/N175
D. E197/L198
E. K215/V216
F. A227/G228
G. G253/K254

Note: If applicant elects a fusion protein (see subgroup 14) wherein said fusion protein possesses a break-point terminus of said β-lactamase that is within ten residues in either direction from a junction, applicant must also elect for the purposes of a search, a ***single*** species of junction from those listed in subgroup 20 above.

Subgroup 21: Species of translocation (claims 44, 47)
If applicant elects a fusion protein (see subgroup 14) wherein said fusion protein possesses an N-terminal signal peptide, applicant must also elect for the purposes of a search, a ***single*** species of translocation corresponding to the signal peptide i.e., bacterial cell periplasm, extracellular membrane of a eukaryotic cell, etc.

Subgroup 22: Species of cell (claim 45)
If applicant elects a species of translocation above (see subgroup 21), applicant must also elect for the purposes of a search, a ***single*** species of cell i.e., *E. coli* cell, etc..

Subgroup 23: Species of fusion protein type (claims 48-49, 54)
Applicant must elect for the purposes of a search, a single species of fusion protein type e.g., extracellular protein, cell surface protein, intracellular protein etc.

23. If applicant elects the inventions of Groups VI or VII, applicant is required to elect from the following patentably distinct species. Claim 50 is generic.

Subgroup 24: Species of fusion protein (claim 50)
Applicant is required to elect, for the purposes of a search, a ***single*** fusion protein species. Applicant must specify ***all*** the regions of the ***single*** fusion protein including the first oligopeptide, second oligopeptide, marker, linker, and break-point regions. Applicant must also specify the N-terminal signal peptide region (if any). Furthermore, applicant ***must*** disclose which claims read on the elected fusion protein.

Subgroup 25: Species of detectable signal (claim 50)
Applicant is required to elect, for the purposes of a search, a ***single*** detectable signal species e.g., phenotypic change (specify phenotype), antibiotic resistance (specify antibiotic), etc..

Subgroup 26: Species of third oligopeptide (claim 50)
Applicant is required to elect, for the purposes of a search, a ***single*** third oligopeptide species (if any).

Subgroup 27: Species of library (claim 51)
A. Single chain antibody Fv fragment library
B. Antibody light chain variable region library
C. Peptide library displayed within thioredoxin

Subgroup 28: Species of association (claims 52 and 53)
A. Unimolecular bipartite association
B. Bimolecular tripartite association

24. If applicant elects the invention of Group VIII, applicant is required to elect from the following patentably distinct species. Claim 57 is generic.

Subgroup 29: Species of expression cassette (claim 57)
Applicant is required to elect, for the purposes of a search, a ***single*** species of expression cassette. Applicant must specify ***all*** the regions of the ***single*** species of expression cassette including the promoter region and any regions encoding for the first polypeptide interactor domain, circularly permutated marker, second polypeptide interactor domain, linker region(s) (if any), cysteine residues (if any), and signal peptide (if any). Furthermore, applicant ***must*** disclose which claims read on the elected expression cassette. For example, if applicant elects an expression cassette that encodes for a signal peptide that provides for the translocation to the periplasm of *E. coli*, applicant must indicate that claims 61 and 62 read on this election.

Subgroup 30: Species of translocation (claim 62)
If applicant elects a fusion protein (see subgroup 29) wherein said fusion protein possesses an N-terminal signal peptide, applicant must also elect for the purposes of a search, a ***single*** species of translocation corresponding to the signal peptide i.e., bacterial cell periplasm, extracellular membrane of a eukaryotic cell, etc.

Subgroup 31: Species of fusion protein type (claim 63)
Applicant must elect for the purposes of a search, a single species of fusion protein type e.g., extracellular protein, cell surface protein, intracellular protein etc.

25. If applicant elects the invention of Group IX, applicant is required to elect from the following patentably distinct species. Claim 58 is generic.

Subgroup 32: Species of expression cassette for third polypeptide (claim 58)
Applicant is required to elect, for the purposes of a search, a ***single*** species of expression cassettee that encodes for the third polypeptide. Applicant must specify ***all*** the regions of the ***single*** expression cassette for the third polypeptide. Applicant must also specify the N-terminal signal sequence portion (if any). Furthermore, applicant ***must*** disclose which claims read on the elected expression cassette.

26. If applicant elects the invention of Group X, applicant is required to elect from the following patentably distinct species. Claim 66 is generic.

Subgroup 33: Species of plasmid (claim 66)
Applicant is required to elect, for the purposes of a search, a ***single*** species of plasmid. Applicant must specify ***all*** the regions of the ***single*** species of plasmid including the fusion protein region. Furthermore, applicant must specify ***all*** the regions of the fusion

protein region including the promoter region and any regions encoding for the first polypeptide interactor domain, circularly permutated marker, second polypeptide interactor domain, linker region(s) (if any), cysteine residues (if any), and signal peptide (if any). Furthermore, applicant ***must*** disclose which claims read on the elected plasmid.

27. If applicant elects the invention of Group XI, applicant is required to elect from the following patentably distinct species. Claim 67 is generic.

Subgroup 34: Species of plasmid (claim 67)
Applicant is required to elect, for the purposes of a search, a ***single*** species of plasmid. Applicant must specify ***all*** the regions of the ***single*** species of plasmid including the "third protein" region. Furthermore, applicant ***must*** disclose which claims read on the elected plasmid.

28. If applicant elects the invention of Group XII, applicant is required to elect from the following patentably distinct species. Claim 68 is generic.

Subgroup 35: Species of host cell (claim 68)
Applicant is required to elect, for the purposes of a search, a ***single*** species of host cell e.g., *E. coli*. Furthermore, applicant ***must*** disclose which claims read on the elected plasmid.

Subgroup 36: Species of plasmid (claim 68)
Applicant is required to elect, for the purposes of a search, a ***single*** species of plasmid that is contained within the host cell. Applicant must specify ***all*** the regions of the ***single*** species of plasmid including the fusion protein region. Furthermore, applicant must specify ***all*** the regions of the fusion protein region including the promoter region and any regions encoding for the first polypeptide interactor domain, circularly permutated marker, second polypeptide interactor domain, linker region(s) (if any), cysteine residues (if any), and signal peptide (if any). Furthermore, applicant ***must*** disclose which claims read on the elected plasmid.

29. If applicant elects the invention of Group XIII, applicant is required to elect from the following patentably distinct species. Claim 69 is generic.

Subgroup 37: Species of host cell (claim 69)
Applicant is required to elect, for the purposes of a search, a ***single*** species of host cell e.g., *E. coli*. Furthermore, applicant ***must*** disclose which claims read on the elected plasmid.

Subgroup 38: Species of plasmid (claim 69)
Applicant is required to elect, for the purposes of a search, a ***single*** species of plasmid that is contained within the host cell. Applicant must specify ***all*** the regions of the ***single*** species of plasmid encoding the "third protein." Furthermore, applicant ***must*** disclose which claims read on the elected plasmid.

30. If applicant elects the invention of Group XIV, applicant is required to elect from the following patentably distinct species. Claim 76 is generic.

Subgroup 39: Species of fusion protein (claim 76)
Applicant is required to elect, for the purposes of a search, a ***single*** fusion protein species. Applicant must specify ***all*** the regions of the ***single*** fusion protein including the first oligopeptide, second oligopeptide, marker, linker(s), and break-point regions. Applicant must also specify the N-terminal signal peptide region (if any). Furthermore, applicant ***must*** disclose which claims read on the elected fusion protein. For example, if applicant elects a fusion protein with a tyrosine kinase (Her-2/neu) in the first oligopeptide region, applicant ***must*** indicate that claims 77 and 78 would read on this election.

Subgroup 40: Species of state of phosphorylation (claim 79)
A. Phosphorylated
B. Unphosphorylated

31. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. Consequently, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

32. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

33. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

34. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

35. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

36. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

37. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

38. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D. Epperson, Ph.D. whose telephone number is (703) 308-2423. The examiner can normally be reached on Monday-Friday from 8:30 a.m. to 4:30 p.m..

40. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jon D. Epperson, Ph.D.
5/20/02

JOSEPH K. McKANE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600